

REMARKS

Status of the Claims

Claims 22 and 24 are pending in the application. Claims 22 and 24 are rejected. Claims 1-23 and 25-52 were canceled. Claims 22 and 24 are amended. Claims 53-56 are added; no new matter is added by these claims.

Notice of Appeal

A Notice of Appeal was filed on January 28, 2005 for the above-referenced application. However, Applicants file a Request for Continued Examination with the present claim amendments for the above-referenced application.

Claim Amendments

Claims 22 and 24 are amended and new claims 53-56 are added so that the subject matter in these claims limit the TADG-15 protein bound by the antibody with regards to the size of the protein (page 64, lines 8-17) and the domains within the protein (Figure 4, page 60, line 15-page 61, line 8) so as to clearly delineate the novelty and non-obviousness of the Applicants' claimed subject matter. Applicants submit that no new matter is added by the subject matter in claims 22 and 24.

Amended claim 22 is directed to a kit for detecting Tumor Antigen Derived Gene-15 (TADG-15) protein. This kit comprises an antibody specific for

a TADG-15 protein, where the TADG-15 protein has a molecular size of 100kDa and comprises CUB, LDLR and serine protease domains. This kit also comprises detectable labels. Amended claim 24 is directed to an antibody specific for a Tumor Antigen Derived Gene-15 (TADG-15) protein, where the TADG-15 protein has a molecular size of 100kDa and comprises CUB, LDLR and serine protease domains.

Newly added claim 53 is directed to a kit for detecting Tumor Antigen Derived Gene-15 (TADG-15) protein. This kit comprises an antibody specific for a TADG-15 protein, where the TADG-15 protein has a molecular size of 100kDa and detectable labels to label the antibody. Newly added claim 54 is directed to an antibody specific for a Tumor Antigen Derived Gene-15 (TADG-15) protein, where the TADG-15 protein has a molecular size of 100kDa.

Furthermore, newly added claim 55 is directed to a kit for detecting Tumor Antigen Derived Gene-15 (TADG-15) protein. This kit comprises an antibody specific for a TADG-15 protein, where the TADG-15 protein comprises CUB, LDLR and serine protease domains and detectable labels to label the antibody. Newly added claim 56 is directed to an antibody specific for a Tumor Antigen Derived Gene-15 (TADG-15) protein, where the TADG-15 protein comprises CUB, LDLR and serine protease domains.

The 35 U.S.C. §102(b) rejection

Claim 22 stands rejected under 35 U.S.C. §102(b) as anticipated by J09149790-A. Applicants respectfully traverse this rejection.

In the Advisory Action mailed January 31, 2005, the Examiner stated that claim 22 was not allowed since the Applicants' claims did not include limitations that set forth a particular domain of TADG-15 protein that should be bound or not bound by the antibody. Further, the Examiner stated that the sequence alignment between Applicants' SEQ ID No. 2 and accession database number W22987 from **J09149790-A** as well as the disclosure in the Japanese document read on Applicants' claims. Hence, the Examiner maintained the 35 U.S.C. 102(b) rejection of claim 22.

In response, Applicants would like to respectfully point out that the accession database number W22987 from the **J09149790-A** reveals a 241 amino acid fragment which is similar to the amino acid residues 615-673 and 675-855 within the serine protease domain of the Applicants' TADG-15 protein. This serine protease domain, however, is just a part of the TADG-15 protein, which also comprises regions in addition to the serine protease domain (amino acid 615-855), such as a cytoplasmic domain (residues 1-54), a transmembrane domain (residues 55-57), a CUB repeat (residues 214-447) and an LDL receptor ligand binding repeat (class A motif) like domain (residues 453-602) (Figure 4, page 60, line 15-page 61, line 8).

Additionally, the specification of the instant invention also teaches that western blot analysis to examine the expression of the TADG-15 protein revealed several bands including bands of approximately 100kDa, 60kDa and 32kDa. It further teaches that the molecular size of the complete TADG-15 protein is 100kDa, that of the protease domain released is 32kDa and an

intermediate product is 60kDa (page 64, lines 8-17). The amended claims and the newly added claims in the instant invention are directed to an antibody specific to TADG-15 protein that has molecular size of 100kDa and comprises CUB, LDLR and serine protease domains which are different from the antibody disclosed in **J09149790-A**. Therefore, **J09149790-A** does not teach each and every element of the amended claims 22 and 24 nor the newly added claims 53 and 56. Accordingly based on the arguments and amendments presented herein, Applicants request that the rejection of these claims under 35 U.S.C. §102(b) be withdrawn.

The 35 U.S.C. §103(a) rejection

Claims 22 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over **J09149790-A** in view of **Harlow and Lane** (Antibodies, A laboratory Manual, pages 319, 321-325 and 340-352, 1988). Applicants respectfully traverse this rejection.

In the Advisory Action mailed January 31, 2005, the Examiner maintained the rejection of claims 22 and 24 under 35 U.S.C. 103(a) for the reasons discussed above. As discussed, the protein disclosed in **J09149790-A** is similar to the serine protease domain of the Applicants' TADG-15 protein. Further as discussed above, the instant invention also teaches the presence of proteins of different molecular sizes in samples that were used to examine the expression of the TADG-15 protein. It is well-known in the art of protein chemistry that each protein folds in a different manner and therefore the residues

that are exposed subsequent to such folding will differ from one protein to another. Therefore, an antibody generated against the protein disclosed in **J09149790-A** will bind to the isolated serine protease domain but may not bind the TADG-15 protein having a molecular size of 100kDa and comprising domains such as CUB, LDLR and serine protease domains as recited in claims 22, 24, 53-56. Therefore, a person having ordinary skill in this art would find no motivation or suggestion in the teachings of **J09149790-A** to generate an antibody that could be used to detect TADG-15 protein as recited in these claims of the instant invention. *Arguendo*, even should one of ordinary skill in the art be motivated by **J09149790-A**, one would be merely trying absent teachings or suggestions of the instant invention to generate an antibody that is specific for the TADG-15 protein as claimed in the instant invention. It has long been established that "obvious to try" is not the legal standard for obviousness.

Applicants assert that obviousness requires that the prior art relied upon fairly teach or suggest all the elements of the instant invention and that an incentive or motivation be present in the prior art to produce the claimed invention with reasonable expectation of success in its production. **J09149790-A** does not teach or suggest elements of the amended claims 22 and 24 nor the newly added claims 53-56 and therefore the combined teachings of the two cited prior arts do not teach or suggest these claims. Further, Applicants have shown that there is no motivation present in **J09149790-A** to produce the claimed invention with reasonable expectation of success and therefore there is no motivation in the combined teachings of the two cited prior arts to arrive at the

instant invention as claimed. Therefore, the subject matter of the amended claims 22 and 24 and the newly added claims 53-56 are non-obvious in view of any combination of the cited prior art references. Accordingly based on the amendments and arguments presented herein, Applicants request the withdrawal of 35 U.S.C. 103(a) rejections of claims 22 and 24.

This is intended to be a complete response to the Advisory Action, mailed January 31, 2005 and supplemental to the Final Office Action, mailed July 27, 2004. Applicants submit that the pending claims are in condition for allowance. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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